

We Claim:

- 1 1. A pharmaceutical composition comprising paroxetine, microcrystalline cellulose,
2 and one or more additional pharmaceutically acceptable inert excipients, wherein
3 the pharmaceutical composition is prepared by a wet granulation technique.
- 1 2. The pharmaceutical composition according to claim 1, wherein the paroxetine
2 comprises free paroxetine base and pharmaceutically acceptable salts, hydrates and
3 solvates thereof.
- 1 3. The pharmaceutical composition according to claim 2, wherein the
2 pharmaceutically acceptable salt comprises hydrochloride, maleate, acetate and
3 mesylate.
- 1 4. The pharmaceutical composition according to claim 1, wherein the concentration
2 of microcrystalline cellulose comprises from about 15% to about 45% by weight.
- 1 5. The pharmaceutical composition according to claim 4, wherein the concentration
2 of the microcrystalline cellulose comprises about 30% by weight.
- 1 6. The pharmaceutical composition according to claim 1, wherein the
2 pharmaceutically acceptable inert excipient comprises one or more of fillers,
3 binders, disintegrants, wetting agents, stabilizers, lubricants / glidants, flavoring
4 agents and coloring agents.
- 1 7. The pharmaceutical composition according to claim 1, wherein the wet granulation
2 is carried out using one or more water miscible solvents, with or without water.
- 1 8. The pharmaceutical composition according to claim 7, wherein the water miscible
2 solvent comprises lower alcohols and lower ketones.
- 1 9. The pharmaceutical composition according to claim 8, wherein the lower alcohols
2 comprise one or both of ethanol and isopropyl alcohol.
- 1 10. The pharmaceutical composition according to claim 8, wherein the water miscible
2 solvent comprises a mixture of water and isopropyl alcohol.
- 1 11. The pharmaceutical composition according to claim 1, wherein the composition
2 comprises a tablet, capsule, caplet, spheroid, or granule.
- 1 12. The pharmaceutical composition according to claim 1, wherein the pharmaceutical
2 composition further comprises a non-functional film-forming polymer coating.

- 1 13. A modified release pharmaceutical composition comprising paroxetine,
2 microcrystalline cellulose, at least one modified release polymer, and one or more
3 pharmaceutically acceptable inert excipients, wherein the pharmaceutical
4 composition is prepared by wet granulation technique.
- 1 14. The modified release pharmaceutical composition according to claim 13, wherein
2 the modified release polymer comprises one or more of cellulose derivatives,
3 alginic acid derivatives, methacrylic acid derivatives, polysaccharides, and
4 alkylene oxides.
- 1 15. The modified release pharmaceutical composition according to claims 13, wherein
2 the paroxetine comprises free paroxetine base and pharmaceutically acceptable
3 salts, hydrates and solvates thereof.
- 1 16. The modified release pharmaceutical composition according to claim 13, wherein
2 the concentration of microcrystalline cellulose comprises from about 15% to about
3 45% by weight.
- 1 17. The modified release pharmaceutical composition according to claim 13, wherein
2 the modified release polymer comprises hydroxypropyl methylcellulose of one or
3 more of the low, medium and high viscosity grades of hydroxypropyl
4 methylcellulose and mixtures thereof.
- 1 18. The modified release pharmaceutical composition according to claim 17, wherein
2 the concentration of the hydroxypropyl methylcellulose comprises from about 10%
3 to about 30% by weight of the total composition weight.
- 1 19. The modified release pharmaceutical composition according to claim 13, wherein
2 the one or more pharmaceutically acceptable inert excipient comprises one or more
3 of fillers, binders, disintegrants, wetting agents, stabilizers, lubricants / glidants,
4 flavoring agents and coloring agents.
- 1 20. The modified release pharmaceutical composition according to claim 13, wherein
2 the wet granulation is carried out using a water miscible solvent, with or without
3 water.
- 1 21. The modified release pharmaceutical composition according to claim 20, wherein
2 the water miscible solvent comprises lower alcohols and lower ketones.

- 1 22. The modified release pharmaceutical composition according to claims 29, wherein
2 the water miscible solvent comprises a mixture of water and isopropyl alcohol.
- 1 23. The modified release pharmaceutical composition according to claims 16, wherein
2 the pharmaceutical composition comprises a solid dosage form.
- 1 24. The modified release pharmaceutical composition according to claim 23, wherein
2 the solid dosage form comprises tablets, capsules, caplets, spheroids, and granules.
- 1 25. The modified release pharmaceutical composition according to claims 13, wherein
2 the pharmaceutical composition further comprises an enteric polymer coating.
- 1 26. The modified release pharmaceutical composition according to claim 25, wherein
2 the enteric polymer comprises one or more of cellulose acetate phthalate, cellulose
3 acetate, hydroxypropyl methylcellulose acetate phthalate, polyvinyl acetate
4 phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl
5 methylcellulose acetate succinate, and one or more methacrylic acid copolymers.
- 1 27. The modified release pharmaceutical composition according to claim 25, wherein
2 the enteric polymer coating comprises about 1% to about 10% w/w of the total
3 weight of the uncoated composition.
- 1 28. The modified release pharmaceutical composition according to claim 13, wherein
2 the pharmaceutical composition further comprises a non functional film coating.
- 1 29. A process for the preparation of a pharmaceutical composition of paroxetine, the
2 process comprising
- 3 (a) blending paroxetine, microcrystalline cellulose, and one or more
4 pharmaceutically acceptable excipients to form a blend;
- 5 (b) wet granulating the blend to form granules;
- 6 (c) drying and sizing the granules; and,
- 7 (d) lubricating and processing the granules into a solid dosage form.
- 1 30. A process for the preparation of a modified release pharmaceutical composition of
2 paroxetine, the process comprising:
- 3 (a) blending paroxetine with microcrystalline cellulose, hydroxypropyl
4 methylcellulose, and one or more of fillers, binders and disintegrants to form
5 a blend;

- 6 (b) wet granulating the blend to form granules;
7 (c) drying and sizing the granules; and
8 (d) lubricating the granules and compressing into tablets.
- 1 31. The process of claim 30, further comprising:
2 (e) coating the tablet with one or more enteric polymers up to a weight gain of
3 about 10% w/w; and,
4 (f) film coating up to a weight gain of about 3% w/w.
- 1 32. A pharmaceutical composition including granules, the granules comprising
2 paroxetine and microcrystalline cellulose, wherein the granules are prepared by a
3 wet granulation technique.
- 1 33. A method of treating depression in a subject in need thereof, the method
2 comprising administering a pharmaceutical composition comprising paroxetine,
3 microcrystalline cellulose, and one or more pharmaceutically acceptable inert
4 excipients, wherein the pharmaceutical composition is prepared by wet granulation
5 technique.
- 1 34. The method of claim 33, wherein at least one of the pharmaceutically acceptable
2 inert excipients comprises hydroxypropyl methylcellulose and the pharmaceutical
3 composition comprises a modified release pharmaceutical composition.